Original Article

Implementation of Informed Consent in Obstetrics and Gynecology Operations in Khartoum- Sudan 2009

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Abstract:-

Objectives: - This is a descriptive, cross-sectional study, done in Khartoum state to assess patients and providers' knowledge and practice on informed consent in obstetrics and gynecology operations during year 2009.

Methodology:- After an informed consent from patients and hospital directorate, data was collected by interview of both patients and health care providers at department of obstetrics and gynecology in all Khartoum state hospitals, during the period from first of January to 31st of December 2009.

Results: - In this study, 544 patients and 393 health care providers were included. Informed consent is known to be important to 355 (90.3%) of health care providers, its contents are wholly or partially known to 263 (66.9%). It was taken for surgical operation by 298 (75.8%) of providers, it was written in 279/ 298 (93.6%) and verbal in 19 /298 (06.4%). Written consent was signed by the husband, the patient herself or her relatives. Lack of time and language are the main reasons for, not taking an informed consent.

Conclusion: - Although informed consent is relatively implemented; its requirements were not properly fulfilled. Not taking an informed consent is influenced by multifactorial barriers including lack of time, language and lack of experience. Pre and in-service training on informed consent and communication skills, with detailed format of informed consent will improve the situation.

Keywords: labour, medical ethics, legal litigations.

An informed consent is a voluntary unforced decision made by a competent autonomous person to accept rather than to reject some purpose or course of action, based on appreciation and understanding of facts and implications of action, even if refusal may result in harm[1]. It is an ethical obligation that recently has become integral to contemporary medical ethics and practice. First case defining informed consent appeared in late 1950s[2, 3]. It is important that the procedure of communication itself is thoroughly documented in patient's notes. Responsibility of obtaining consent belongs to physician providing treatment; delegates should be trained, informed and qualified to the task[4].

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Consent should be written, when possible, if not, a verbal consent must be documented and witnessed[4]. Ideally, it should be signed by the patient, a surrogate or a proxy when the patient is unable to sign e.g. below legal age, mentally retarded, unconscious, or under medication. When there is no surrogate or a proxy, physician is expected to act on the best interest of the patient.

In obstetrics and gynecology, informed consent, is becoming important due to expanded and interconnected medical options, public health problems, legal litigations and political agenda. However, implementation in many times faces challenges, as in labour and delivery, adolescents, sexuality and reproduction, genetic counseling and patient's wellbeing and rights of choice. This affects both health care providers and patients. None of these challenges makes the achievement of informed consent impossible, but alerts obstetricians to identify the condition and its limits[5]. In Sudan, verbal or implied consent

had been adopted for medical practice, long time ago. During last two decades, as health services expand and health education and public awareness about their rights for having access to good quality of care rises, people became less tolerant to medical errors and more conflict rises that affect the practice of medicine. There are no known available data on implementation of informed consent in surgery in Sudan, which necessitates the study. This study aims to assess the patients and health care providers' knowledge on informed consent, its importance and contents, as well as assessing implementation and barriers against implementation of informed consent in obstetrics and gynecology operations.

Methodology: This is a descriptive cross-sectional, hospital based study conducted in 14 hospitals in Khartoum state, during the period from first of January to 31st December 2009. These are general hospitals with departments of obstetrics and gynecology; two of them are specialized maternity hospitals. Obstetrics and gynecology departments in all hospitals were covered by specialists, registrars and house officers, with few medical officers. In each hospital, there are at least, labour ward, antenatal word, referred antenatal clinic, postnatal word, postnatal clinic, gynecological word, theater, blood bank, pharmacy, and laboratory. All doctors providing medical care were included during the year, two rotational shifts, six months each. A list of participants was prepared to avoid double participation of registrars or house officers. Patients subjected to obstetrics and gynecological operations and agreed to be enrolled in the study were included after an informed consent. Data collection from health care providers was done by the authors, while data from patients were collected by a group of trained registrars in each hospital in Khartoum.

Results: In this study, 544 patients and 393 health care providers were included. Among health care providers, 248 (63.1%) were registrars, 106 (29.0%) were house officers and 39 (09.9%) were specialists. Informed consent is known to be important to 355 (90.3%) of health care providers, and 38 (09.7%) did not know its importance for medical practice or medico-legal aspects. The contents of informed consent are wholly or partially known to 263 (66.9%). Informed consent was taken for surgical operation by 298 (75.8%) of providers. All providers had no training on communication skills and informed consent before graduation, however, some of the registrars 102 (41.0%) had training on communication skills during their internship. Providers who took informed consent are those who know the contents and importance of informed consent (Table 1).

Table1: Association between providers' knowledge and implementation of informed consent for obstetrics and gynecology operations in Khartoum 2009.

	Providers who know contents of informed consent N=355 (%)		Providers do not know contents of informed consent N=38 (%)		Total N=393 (%)	
Taking consent	296	(75.3)	02	(0.5)	298	(75.8)
Not taking consent	059	(15.0)	36	(9.2)	095	(24.2)
Total	355	(90.3)	038	(9.7)	393	(100.0)

Chi-square: 3.550, P= 0.000 -

Informed consent taken by providers was written in 279/ 298 (93.6%). Written consent was signed by the husband in 154 /279 (55.2%), by the patient herself in 71/279 (25.4%) and by relatives in 54 /279 (19.4%).

Reasons for providers, not taking an informed consent were attributed to lack of time due to over work especially in emergency by 57 /95 (60.0%), language barriers 26 /95 (27.4%) and other none specified barriers 12/95(12.6%)

Patients included in the study were 544, their age mainly between 20-40 years (Table 2).

Table 2: Distribution of patients participated in study of informed consent in obstetrics and gynecology operations in Khartoum 2009 according to age.

Age in years	N=544 (%)
Less than 20	023 (04.2)
20- 30 years	311 (57.2)
31-40 years	178 (32.7)
More than 40	032 (05.9)
Total	544 (100.0)

One hundred forty one (25.9%) were illiterate, 339 (62.3%) at secondary school and 64 (11.8%) were university students or graduate. Informed consent taken, more among educated than illiterate participants (Table 3). Most of them 512 (94.1%) were Arabic speakers. Informed consent was taken for 313 (57.5%). Only 18 (03.3%) of patients know something about informed consent. Patients in the study, 408 (75.0%) were satisfied by the service they received. Patients' satisfaction was not affected by having an informed consent or not (Table 4).

Table3: Association of having an informed consent for obstetrics & gynecology operations & patient's education in Khartoum 2009.

Level of education	Have informed consent N=313 (%)		Have no informed consent N=231(%)		Total N=544(%)
Illiterate	039	(07.2)	102	(18.7)	141(25.9)
Secondary school	232	(42.6)	107	(19.7)	339(62.3)
University	042	(07.7)	022	(04.1)	064(11.8)
Total	313	(57.5)	231	(42.5)	544(100.0)

Chi- square: - 69.714, P = 0.000

Table4: Association of patients' satisfaction & taking of informed consent in obstetrics and gynecology operations in Khartoum 2009.

	Satisfied N=408(%)		Not satisfied N=136(%)		Total N=544(%)	
Have a consent	244	(44.8)	069	(12.7)	313	(57.5)
Have no consent	164	(30.2)	067	(12.3)	231	(42.5)
Total	408	(75.0)	136	(25.0)	544	(100.0)

Chi- square: 3.433, P = 0.0639.

Discussion:-

Informed consent is an important tool for improvement of patient care. This study showed that a considerable number of health care providers do not know the contents and importance of informed consent and they did not implement during their patient care. This may be influenced by doctors' experience, time, and patients' awareness on the importance of informed consent in participation in decision making. Adequate utilization and information for informed consent depends on physician's knowledge and how it is conveyed to patients, and what patient needs to know in order to understand decision. Some patients believe that, informed consent is to protect care providers rather than participation in decision and improving their service. Even in England, patients still have limited understanding of legal aspects of informed consent, which may affect utilization[6].

In this study, lack of time due to over work, especially in emergency department, is the main reason behind not taking an informed

consent (60%). This is relatively high compared to the 22% found in Royal Infirmary Hospital in Edinburgh[7]. Practical difficulties for having good communication are; limitation of time in clinical context, underdeveloped professional communication skills, language barriers, stress situation on all sides and limitation in patients' capacity for a comprehensive choice. Patient's capacity is a difficult complex task, however, informed consent is sometimes an easy process when there is some community awareness on the intervention e.g. withdrawing of blood or doing an episiotomy. Written informed consent, evaluated in this study, was brief, uninformative, containing agreement for operation; however, many of the requirements for informed consent were missing. This may be due to deficient practice of care providers, or lack of adherence to regulations. The available format from Sudan Medical Council, implemented by many hospitals, does not contain detailed information for informed consent. This is not the case found in USA, where surgeons provide detailed description of the risks and alternatives to surgery before operation[8]. Informed consent is not simply getting a patient to sign a written consent form, but involves a process of dynamic good communication between patient and physician resulting in authentication and agreement for specific medical intervention[9]. Patient should have an opportunity to ask questions to elicit a better understanding of treatment and procedure enabling for informed decision to proceed or to refuse a particular intervention. A well designed informed consent form may be useful; however, a basal or highly detailed form may be confusing e.g. "all risks have been explained to me". It is important to insert words like "the list is not exclusive"[10]. For improving the existing situation, a new format is to be adopted in both Arabic and English, with detailed information for each type of operation. Stress state associated with illness should not necessary preclude one from participating in her care, however, precautions should be taken to ensure patient's capacity to make good decision. If patient condition is unclear, psychiatric opinion is helpful. Refusal of treatment does not mean the patient is incompetent; it is her right to refuse.

Patients' satisfaction in this study is not affected by level of implementation of informed consent (Table 4). This is consistent with study done in India, where 45% of patients given informed consent; while 78% of the study group was satisfied with the service they received[11]. Some studies done in Ireland and Britin 2001, showed that demographics are minor factors in patient's satisfaction, while some studies done in New York 2000, found that individuals of lower educational level tend to be less satisfied with their care providers[12]. In many medical errors, poor consent was identified as the root cause of inadequate treatment and poor satisfaction. A study done in New York 2000 showed that, patients who were treated with dignity and involved in decision, were more satisfied and adherent to their doctor's recommendations[13].

Conclusion: Although informed consent is relatively implemented; its requirements were not properly fulfilled. Not taking an informed consent is influenced by multifactorial barriers including lack of time, language and lack of experience. Pre and in-service training on informed consent and communication skills, with detailed format of informed consent will improve the situation.

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